UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,910	03/30/2001	Daniel J. Balbierz	13724-845	7532

22918 7590 06/03/2003

PERKINS COIE LLP
P.O. BOX 2168
MENLO PARK, CA 94026

EXAMINER
VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 06/03/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary	Application No.	Applicant(s)	
	09/823,910	BALBIERZ ET AL.	
	Examiner	Art Unit	
	Peter J Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,18,19,23-25,29,31-37,39-44,47,48,53,57,58,69,74,75,77,82-84 and 89* is/are rejected.

7)☒ Claim(s) *59-62,67,68,70-73,92,93 and 95-99* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

Continuation of Disposition of Claims: Claims pending in the application are 1-9,11,18,19,23-25,29,31-37,39-44,47,48,53,57-62,67-75,77,82-84,89,92,93 and 95-99.

DETAILED ACTION

Applicant has filed Amendment B.

Claims 10,12-17,20-22,26-28,30,38,45-46,49-52,54-56,63-66,76,78-81,85-88,90-91,94,100-104 are cancelled.

Typographical errors regarding claim dependency are currently found in claims 11 and 77. Correction by Applicant is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-9,11,18-19,23-25,29,31-37,39, 42-44, 57-58, 69, 74-75, 77, 82-84, and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Benaron et al. ('609).

Gough et al. (Gough) discloses a method for treating a tumor comprising:

providing a tissue biopsy and treatment apparatus especially in figure 3 comprising an elongated delivery device (10) including a lumen (14); a deployable sensor array (24) including a plurality of resilient members (18) deployable with curvature (see figure 3), the sensor array having a geometric configuration (depicted in figure 3) adapted to volumetrically sample tissue at a tissue site or multiple tissue sites

to differentiate or identify tissue including tumor boundaries (col. 4:63-67) at the tissue site(s) during an energy delivery interval (col. 6: 28-33); an energy delivery device (12,14,16, 20) coupled to (or comprising) the resilient members (18);

introducing the apparatus into a target tissue site (col. 2:22-25);

distinguishing a tissue type (ex. tumorous) utilizing the sensor array (col. 4:63-67 and col. 6:33-34);

positioning or *maneuvering* the energy delivery device utilizing tissue type information derived from the sensor array to ablate or necrose a tumor volume (col. 6:64-66);

delivering energy from the energy delivery device to ablate or necrose at least a portion of the tumor volume (col. 7:5-7);

determining an amount of tumor volume ablation utilizing the sensor array (col. 6:28-33).

Re: claims 2 and 6, Gough discloses monitoring tissue volumes (col. 6: 28-33, iv).

Re: claims 6-8, 5, and 25,Gough discloses monitoring at least a first and second tissue volume represented by tissue volumes proximal to each sensor (24, fig. 3). Further, Gough discloses monitoring tissue volume within a tumor (28) and outside ("adjacent") a tumor. Note column 8 lines 57-61. This specific disclosure makes inherent that differentiating between tissue types is occurring between a selected tissue mass and a non-selected tissue mass. Also, made inherent is that a determination of a

healthy tissue (non-tumerous, non-selected) ablative margin (analogous to tumor boundary) is made by the logic resources (col. 9:49-57). Lastly, note that Gough establishes equivalency between a tumor and a selected tissue mass in column 4 lines 63-67.

Re: claims 9,11 and 89, Gough discloses a multiplexer to measure and compare parameters at the numerous sensors (24) each providing measurements including temperature from different tissue volumes. Fig. 3 depicts sensors (24) along different portions of delivery device (10). Therefore, monitoring will occur at numerous locations throughout the delivery device. Further, some of the sensors are in closer lateral proximity to the energy delivery device (14) than others (clearly illustrated in figure 3).

Re: claims 3,5, 29, 34, and 35, Gough discloses logic resources or processor (38, fig. 9, 50. fig. 10) coupled to a power source (20). Power is adjusted in response to an input from the sensor array (col. 6:48-54).

Re: claims 4, 32, and 77, tissue temperature or tissue impedance is monitored (col. 6: 42-44).

Re: claims 18,19,33,37, and 74, Gough discloses locating a tumor volume (boundaries) utilizing the sensor array (col. 4:63-67 and col. 6:33-34).

Re: claims 23, 24, 39, 42, and 44, Gough discloses determining the amount of tissue necrosis or a treatment endpoint utilizing the sensor array (col. 6: 28-33).

Re: claims 31 and 36, Gough discloses a database (col. 10:32-33).

Re: claim 43, Gough discloses titrating a tissue treatment based on information derived from a tissue property (col. 6:28-33, especially iii).

Re: claims 57, 58, and 69, Gough discloses chemotherapeutic marking agents (col. 9:22-30).

Re: claim 83 and 84, Gough discloses infusion of marking agents (conductivity enhancement mediums) to enhance delivery of energy and thermal injury to the tumor (col. 9:25-28).

Re: claim 75, Gough discloses RF electrodes (col. 6:10-13).

Gough neglects to disclose a spectral profile measurement.

Benaron et al. (Benaron) discloses an analogous tumor treatment method comprising the use of a spectrophotometer (col. 8:42-53; col. 9:13-20), permitting spectral profile measurements of targeted tissue. The Applicant also uses a spectrophotometer to undertake spectral profile measurements as submitted in the Specification page 16 line 13.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Gough in view of Benaron by including as a design expedient a spectrophotometer. The motivation to do so would be as posited by Benaron in col. 8:49-53, "to minimize risk of collateral damage or incomplete treatment, and to maximize success..."

2. Claims 47,48, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Benaron and further in view of Hoey et al. ('722).

Gough and Benaron neglect to disclose baseline measurements.

Hoey et al. (Hoey) discloses an analogous electrode tissue ablation method in which *baseline impedance measurements* (232) are taken as depicted in figure 11. Further, Hoey discloses comparing (226,240) impedance measurements throughout the surgery and adjusting (228,246) energy delivery parameters (RF power), accordingly, which further affect tissue ablation time and volume.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Gough in view of Benaron and further in view of Hoey by including as a method step, that of obtaining and using impedance measurements to guide effective surgery. The motivation would be to "safeguard the patient and the apparatus," as submitted in Hoey col. 23:20-21.

3. Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Benaron and further in view of Edwards ('528).

Gough and Benaron neglect to disclose making a diagnosis based on measured a tissue property.

Edwards discloses an analogous electrode tissue ablation method in which *a diagnosis based on a measured tissue property (impedance) is made*. Note column 9:9-20; iii.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Gough in view of Benaron and further in view of Edwards by making a diagnosis using measurements of tissue property. The motivation would obviously be to afford the surgeon insight with regards to the condition of the patient in order to develop an effective plan for surgical intervention.

Allowable Subject Matter

Claims 59-62, 67-68, 70-73, 92-93 and 95-99 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to independent claims 1 and 57 have been considered but are moot in view of the new ground(s) of rejection.

Benaron is presented above by the Examiner in response to the new issue introduced into independent claims 1 and 57 (spectral profile measurement). Benaron uses a spectrophotometer to measure targeted tissue spectral profiles.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

Pete Vrettakos
May 23, 2003

LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700